

# 公司认证

## Company Certification



### Certificate of Registration

The Governing Board of  
INTERNATIONAL STANDARDS CERTIFICATION LIMITED  
hereby grants to:

#### Nanning TECBOD Biological Technology Co.,Ltd.

Address: Room 601 Floor 6, B2 Building, No 19 Guokai Dadao, Nanning , Guangxi,  
P.R.China

Has been assessed and found to be in accordance with the requirements of  
standard detailed below

#### ISO 13485:2016

##### Scope

Production and Sales of Medical Devices  
(see attachment for products included)

Authorized by: Blena YP-KO



Certificate No.:ISC3485202033042

Initial Certificate Date:2020-03-18      Certificate Expiration Date:2023-03-17

Note:The time interval between each surveillance audit and the last on-site audit shall not exceed 12 months, the certified clients shall accept regular surveillance audit, the validity of certificates shall be maintained for the positive result of audit.



INTERNATIONAL STANDARDS  
CERTIFICATION LIMITED  
ROOM 22,13 F,SPEEDY INDUSTRIAL BUILDING,  
114 HOW MING STREET,KOWLOON,HONG KONG  
Email:info@accredititservice.com.  
Check the validity of certificate at  
[www.accredititservice.com](http://www.accredititservice.com)



INTERNATIONAL STANDARDS CERTIFICATION LIMITED

#### Attachment to Certificate

Certificate No.:ISC3485202033042

#### Organization:

Nanning TECBOD Biological Technology Co.,Ltd.  
Room 601 Floor 6, B2 Building, No 19 Guokai Dadao,  
Nanning , Guangxi, P.R.China

#### Scope

##### Products:

Medical Protective Clothing  
Disposable isolation gown  
Single-use medical protective overboot  
Single-use medical protective hood  
Clean air suits  
Reusable surgical drapes  
Surgical gowns  
Single-use surgical gowns  
Disposable medical protective bag  
Surgical cap  
Wash clothes  
Medical pads  
Medical face-shield  
Medical goggle  
Latex Examination Gloves

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# CE符合性声明

## CE Declaration of Conformity

File No: CE-TCF-001

### EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)  
including Directive 2007/47/EC

#### Applicant

Name: Nanning TECBOD Biological Technology Co., Ltd  
Address: Room 601 Floor 6, B2 Building, No.19 Guokai Dadao, Nanning , Guangxi, P.R.China



#### EC Representative

Name: SUNGO Europe B.V.  
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

#### Product

Name: Disposable medical protective hood  
Type: I type: Strip cap (cap fold) II type: Flap cap III type: Lace-up cap

Name: Clean air suits  
Type: Conjoined coverall/S、M、L、XL、XXL、XXXL、XXXXL  
Split overalls/S、M、L、XL、XXL、XXXL、XXXXL

Name: Disposable surgical gowns  
Type: S、M、L、XL、XXL、XXXL

Name: Medical face-shield  
Type: Anti-fog type/TKBD2001

Name: Medical goggle  
Type: Anti-fog closed type/TKBD1001

Name: Medical latex examination gloves  
Type: Powder glaz/6、6.5、7、7.5、8、8.5、9  
Powder pitting/6、6.5、7、7.5、8、8.5、9  
Powder Free glaze/6、6.5、7、7.5、8、8.5、9  
Powder Free pitting/6、6.5、7、7.5、8、8.5、9

Classification: Class I (MDD, Annex IX), Rule 1 (All non-invasive devices are in class I)  
Conformity Assessment Route: Annex VII

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012  
EN ISO 15223-1:2016  
EN 1041:2013  
EN 166:2002  
EN 455:2019  
EN 13795-2:2019  
EN 13795-1:2019  
EN ISO 10993-1:2009/AC:2010  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013



# 欧盟授权代表协议

## MDR EU REP Agreement

SUNGO Europe B.V.  
SUNGO/ECR/NED/MDR/01 V2.0

Ref. No.: MDR2020M02081

### MDR EU REP Agreement

**Party A甲方:** Nanning TECBOD Biological Technology Co.,Ltd

**Add地址:** Room 601 Floor 6, B2 Building, No 19 Guokai Dadao, Nanning, Guangxi, P.R.China

**Contact联系人:** 韦丽巧

**Tel电话:** +86 0771-3210918

**Fax传真:** +86 0771-3210918

**Email邮箱:** 2857994237@qq.com

**Party B乙方:** SUNGO Europe B.V.

**VAT:** NL857821659B01

**Add地址:** Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Contact联系人:** SUNGO Secretary

**Tel电话/Fax传真:** +31 (0) 2021 11106

**E-mail邮箱:** ec.rep@sungogroup.com



Party A hereby appoints Party B as the EU authorized Representative for their Medical Device with CE mark and Party B accepts the appointment to be the EU authorized Representative for Party A in the market of European Union (E.U.). Both parties enter this agreement as follow:

甲方任命乙方为CE医疗产品欧盟授权代表，乙方接受甲方任命，为甲方在欧盟市场的CE医疗产品授权代表。双方签署下列协议：

#### 1. Party A 甲方

1.1 Party A assures to provide the updated technical files of each product category with CE mark to Party B (Product categories relevant information please see the appendix A). If Party A can not provide the required technical file to Party B within 30 days after approval of CE certification or before using CE mark for "self declaration" products, this agreement will be terminated automatically, Party A should take on any aftereffect by itself. The technical files should be the electronic copy (PDF/WORD/JPG/TXT version), the written copy would be submitted if required by the competent authority. Detail of the requirements of the submitted files in appendix B.

甲方确保在认证结束后向乙方提供每一大类带CE标志产品的、最新的技术文档（甲方申请CE认证的产品信息见附录一）。如果甲方在认证结束取得证书之后的30天内，或者“自我声明”产品在使用CE标记之前，仍然没有提供给乙方符合要求的CE技术文档的，本协议自动失效，甲方承担由此引起的所有后果。甲方必须提交电子文档文件，文件可以PDF/WORD/JPG/TXT格式的任何一种提交。书面文件只有在欧盟当局需要审核时才提交乙方。所提交文档内容的要求，详见本协议“附件二”。

1.2 Party A shall keep the Party B informed of any changes or updates of the mentioned information in attachment 1 at all times.

如果附件1中的文件有任何变化或更新，甲方应及时通知乙方。

1.3 If any accident/near accident of products, including any serious adverse event during clinical investigation in premarket stage, happens within boundary of E.U., Party A shall help Party B

SUNGO Europe B.V.  
SUNGO/ECR/NED/MDR/01 V2.0

#### Appendix A

For the following product categories:

申请CE认证的产品名称：

No.	Product name 产品名称	Product classification 产品分类	Product name in Chinese 中文产品名称
1	Disposable medical protective hood	I	医用帽（非灭菌）
2	Clean air suits	I	洁净服（非灭菌）
3	Disposable surgical gowns	I	一次性使用手术衣 (非灭菌)
4	Medical face-shield	I	医用隔离面罩（非无菌）
5	Medical goggle	I	医用隔离眼罩（非无菌）
6	Medical latex examination gloves	I	医用橡胶检查手套（非无菌）

# FDA注册注明

## FDA registration confirmation

### FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the **Fiscal Year 2020** of

**NANNING TECBOD BIOLOGICAL TECHNOLOGY CO., LTD**  
Room 601 Floor 6, B2 Building, No 19 Guokai Dadao Nanning,  
Guangxi, 530033, CHINA

The facility registration and device listing information:

Owner/Operator Number: 10067979		
Device Listing No.	Product Code	Product Name(s)
D387308	OEA	Protective clothing, Isolation Gown,Clean air suits
D387311	HOY	Medical goggle
D387327	FXP	Shoe cover
D387331	LYU	Glove
D387333	FYE	Disposable surgical gown,surgical gown
D387334	KPY	Face-Shield
D387337	FYF	Medical cap

*SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this attestation until the end of the calendar year stated above, unless said registration is terminated after issuance of this attestation. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this attestation make any representations or warranties to any person or entity other than the named attestation holder, for whose sole benefit it is issued. This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.*

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a attestation of registration, nor does the U.S. Food and Drug Administration recognize a attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.*

Reference Number: 2007US233518  
Issue date: Apr.08, 2020

**SUNGO Technical Service Inc.**  
6050 W EASTWOOD AVE APT 201  
CHICAGO, ILLINOIS 60630, USA  
sungo.group@yahoo.com



# 产品信息

## product information

产品名称	规格型号	执行标准	国际认证	日产量	功能特点	用途	材质	装箱规格	外箱尺寸	净重/毛重
一次性使用手术衣	S/M/L/XL/XXL	YY/T0506 EN13795	ISO13485:2016 CE符合性声明 FDA注册	20万件	防水、阻菌、不脱絮，一次性使用	防止医生身体上的皮屑弥散到开放的手术创面和手术病人的体液向医务人员传播，起到双向生物防护的作用。	SMS	70件/箱	80*40*52(cm)	9kg/11.5kg

Product name	Models & Specifications	Execution standard	International certification	Daily output	Functional features	Application scope	The material	Packing specification	Carton size	NW/GW
Disposable Surgical Gowns	S/M/L/XL/XXL	YY/T0506 EN13795	ISO13485:2016 <b>CE Declaration of Conformity</b> FDA	200,000 pieces	Water-proof, anti-bacteria, anti-static, disposable	<p>It is used to wear on the surgeon and the nurse to prevent the dandruff on the doctor's body from spreading to the open surgical wounds and the body fluid of the surgical patient from spreading to the medical staff, playing the role of bidirectional biological protection. The product is not sterilized when it leaves the factory. It must be sterilized by the user before use. It can be reused after sterilization.</p>	SMS	70pcs / carton	80*40*52(cm)	9kg/11.5kg